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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,817	07/18/2003	Olga Corti	FRAV2002/0020US NP	3025

5487 7590 04/08/2005

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,817	CORTI ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *10-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/4/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election without traverse of Invention 1, Claims 1-9 in the reply filed on February 7, 2005 is acknowledged.

Claims 10-23 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions.

Priority is to July 18, 2002.

Upon perusal of the sequences set forth in Claims 8 and 9, it appears that the claims are inappropriately placed and sequences repeated.

NO:	derived from:	protein/DNA	# AAs/NTs	encoded/N-terminal 15 aa
1	human	DNA	1131	MPMYQ VKPYH GGGAP
2	human	protein	320	same
3	human	protein	320	identical to NO: 2
4	mouse	DNA	1233	MPMYQ VKPYH GGSAP
5	mouse	protein	320	same
6	mouse	protein	320	identical to NO: 5
7	human	DNA	2960	MIVFV RFNSS HGFRV
8	human	protein	465	same
9	human	protein	465	identical to NO: 8
10	human	DNA	471	encodes 135-290 of NO: 8 or NO: 9

Note that SEQ ID NOs: 1-6 are drawn to p38, while SEQ ID NO: 7-10 are drawn to parkin. Thus, with regards to art, Claim 8 will be prosecuted as though it references SEQ ID NO: 1 and 4 as encoding p38, and SEQ ID NO: 2, 3, 5, and 6 as p38. Claim 9 will be taken to refer to SEQ ID NO: 7-10. Also, SEQ ID NO: 2 and NO:3, SEQ ID NO: 5 and NO: 6, and SEQ ID NO: 8 and NO: 9 are identical and therefore represent repeated limitations within the claims. In response to this Office Action, Applicants should correct references to these sequences in the claims as well as in the specification (see throughout the specification, and for example at page 7, lines 10+).

The disclosure is objected to because of the following informalities: The cross reference to applications on page 1 needs to be updated to include foreign priority claims to the UK application.

The abstract is 2 paragraphs, rather than the required 1 paragraph.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because reference to "p38" is a pellet identifier. Claim 1 should refer to p38 as being a mitogen activated protein kinase, being careful not to add new matter. Note that reference to Quevillon et al. at page 8, line 19, is not incorporated by reference.

Claim 1 appears to be incomplete because the binding partner of p38 is not set forth. Thus, it is not clear what binding property is being assayed.

Claim 6 is indefinite because Claim 1 refers to a sample which is not regarded as being *in vivo*, to in an animal. The specification does not appear to define "*in vivo*" in other terms. Upon review of the literature and consideration of the limitations of dependent Claim 7, the Examiner has taken "*in vivo*" to refer to within a cell in culture.

Claim 8 and 9 are indefinite due to the mix up of the sequences as set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulevitch et al. (USP 6,010,856, issued January 4, 2000).

Ulevitch et al. teach assay systems for methods for assaying modulators of p38 MAP kinase activity. In Example 2, the physical interaction of p38 and MEF2C (Claim 4) was assayed using solid-phase binding an phosphorylation assays (Claim 5) using γ^{32}P-ATP. Therefore, a method for screening candidates compounds for their effectiveness in modifying the binding properties of p38 by exposing a sample comprising p38 to the candidate compound γ^{32}P-ATP and measuring p38 binding property is taught by Ulevitch et al. (Claim 1).

In Example 1, a yeast two-hybrid system was used to assay (Claims 6, 7).

See all of the Examples, and see Example 5 wherein HeLa cells expressing MEF2C and p38 were exposed to sorbital.

See patent Claim 8-14 wherein Ulevitch et al. claim this method.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulevitch et al. (USP 6,010,856, issued January 4, 2000) and Vogelstein et al. (USP 5,843,757) and/or Nicolaides et al. (1995; Genomics 29: 239-334).

Ulevitch et al. teach assay systems for methods for assaying modulators of p38 MAP kinase activity. In Example 2, the physical interaction of p38 and MEF2C was assayed using solid-phase binding an phosphorylation assays using γ^{32}P-ATP. Therefore, a method for screening candidates compounds for their effectiveness in modifying the binding properties of p38 by

exposing a sample comprising p38 to the candidate compound γ^{32}P-ATP and measuring p38 binding property is taught by Ulevitch et al. (Claim 1).

Ulevitch et al. do not teach the amino acid sequence of the p38 used in their assay.

Vogelstein et al. teach SEQ ID NO:2 from amino acids 1-312 (of 320), or 98.7% identity to SEQ ID NO: 2 and NO: 3 . Nicolaides et al. teach p38 having 100% identity to SEQ ID NO: 2 and NO: 3.

Vogelstein et al. teach p38 having 86.8% identity to SEQ ID NO: 5 or NO: 6.

It would have been obvious to a person having ordinary skill in the art to use any p38 kinase including those taught by Vogelstein et al. or Nicolaides et al. to perform the assay of Ulevitch et al. because Ulevitch et al. use the generic term for p38 instead of specific amino acid sequences because p38 is a well-known kinase.

Claims 2, 3, and 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

No Claims are allowed.

Art of record:

Cohen (1997; Trends in Cell Biology 7:353-361) presents a review article on the many modulators of p38 activity *in vitro* and *in vivo*.

Shimizu et al. (USP 6,716,621; priority to 1998) teach parkin sequences NO: 8 and NO: 9.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Karen Cochrane Carlson, Ph.D.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER